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## **Pakistan**

### **Agricultural Biotechnology Annual**

#### **Agricultural Biotechnology Annual 2013**

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**Report Highlights:**

The Government of Pakistan has recognized the importance of biotechnology as a tool that can help ensure food security and mitigate climate change. Consequently, it has included biotechnology as a key component in its draft “National Food Security and Nutrition Policy”. Nonetheless, the process to approve new genetically engineered varieties has been stalled. Since 2010, no new varieties have been approved at the federal level. Pakistan does not impose trade barriers for the import of GE crops, and in 2012 significant amounts of GE canola, corn, cotton, soybean, soybean meal, and soybean oil were allowed into the country.

## Section I. Executive Summary:

The emergence of Pakistan as the ninth mega country growing genetically engineered (GE) crops, as reported in the International Service for the Acquisition of Agricultural Biotechnology Applications (ISAAA) Briefs 2012, attests to the successful adoption of GE crops in Pakistan. Under the current 2013-14 crop, more than 2.8 million hectares (HA) – 85 percent of total planted area—are under Bt cotton cultivation. To date, it's the only crop that has been approved for commercial cultivation.

Since February 2012, no new varieties of GE cotton have been approved. In 2012, the Punjab Seed Council (PSC) formally approved eight biotech cotton varieties for cultivation in Punjab, though new GE varieties were submitted to the PSC in 2013, these have not been approved due to an outstanding order from the National Biosafety Committee (NBC) stating that product commercialization is a federal undertaking. However, at the federal level no new varieties have been approved since 2010.

Bt varieties under cultivation are Open Pollinated Varieties (OPVs), thus seed is utilized for the next season's planting. Local seed companies are employing conventional breeding tools for seed multiplication, which are certified by the Federal Seed Certification and Registration Department (FSC&RD) of the Ministry of National Food Security and Research (MNFSR).

## Section VII. Author Defined:

### CHAPTER 1: PLANT BIOTECHNOLOGY

#### PART A: PRODUCTION AND TRADE

##### a) PRODUCT DEVELOPMENT:

The current status of development of GE crops is assessed by reviewing ongoing work among different institutes of Pakistan. Crop/trait status of events is given in Table-1

**Table 1: DEVELOPMENT OF GE CROPS IN PAKISTAN**

Crop	Trait	Status
Cotton	Diamondback moth resistance with Bt gene	Field trials
	Virus (CLCV) resistance with Tr AC gene	Field trials/ ready to release
	Virus (CLCV) resistance with RNA interference (RNAi)	Field trials
Wheat	Drought tolerance/ Salt Tolerance	Field trials
	Biofortified Wheat for increased Iron and Zinc bioavailability: Rust resistance markers	Lab/Field experiments
Rice	Bacterial blight resistance with Xa21 gene	Experimental
	Salt tolerance with Yeast and Arabidopsis Na <sup>+</sup> /H <sup>+</sup> antiporter genes	Experimental
	Insect resistance with Cry1Ac & Cry2A genes	Experimental
Maize	Insect Resistance	Field trials
	Herbicide Tolerance	Field trials
	Insect/Herbicide Tolerance	Field trials

Sugarcane	Insect resistance with Cry gene	Experimental
	Chloroplast Transformation	Experimental
Chickpeas	Insect resistance (Bt gene)	Experimental
	Drought & Salt Tolerance with Yeast, Arabidopsis Na <sup>+</sup> /H <sup>+</sup> antiporter genes	Experimental
Brassica	Male sterility through RNAi	Experimental
Tomato	Virus (TLCV) resistance through RNAi	Experimental
	Male sterility through RNAi	Experimental
Tobacco	Insect( <i>Helicoverpa armigera</i> and <i>Heliothis virescens</i> ) with a novel synthetic spider venom gene	Experimental
	Salt Tolerance with Yeast, Arabidopsis Na <sup>+</sup> /H <sup>+</sup> antiporter genes	Experimental
	Salt Tolerance with ArDH	Experimental

**b) COMMERCIAL PRODUCTION:**

During the crop year 2013-14, more than 2.8 million hectares (HA) are under Bt cotton cultivation, utilizing 16 Bt cotton varieties (including one Bt cotton hybrid) , and covering 85 percent of the total cotton cultivated area. The Bt approved varieties contain one of the two released events MON 531(Cry1AC gene) and the GFM event expressing the fusion gene cry1Ac and Cry1Ab.

In 2012, the National Biosafety Committee (NBC) of Pakistan's Environmental Protection Agency (Pak EPA) approved 143 cases for greenhouse and field trials (Table-2). Pakistan's approval process is based on approving the variety and not at the transformation event. As such, many new submissions contain Bt events approved in the past: Cry1Ac and Cry1Ab.

**Table-2: APPROVAL OF GE CASES WITH NBC/ PAK-EPA, GOVERNMENT OF PAKISTAN SINCE 2010**

Total Cases Submitted to the NBC for laboratory, greenhouse, field trial, or commercial approval	223
Cases approved by the NBC	143
Labs + GH + Field Studies	145
Commercial approval	16 Genetically Engineered Cotton Varieties

**c) EXPORTS:**

In 2012, Pakistan exported approximately \$250 million of GE cotton mostly to China, Indonesia, Thailand and Malaysia. Additionally, Pakistan export items include cotton yarn, cotton fabric, and items manufactured from GE cotton which has been produced locally or imported from GE cotton growing countries such as Australia, Brazil, India, and the United States.

In FY 2012/13, the textile sector exported \$13.10 billion worth of textile products.

**d) IMPORTS:**

In 2012, Pakistan imported around two million (480 lb) bales of GE cotton with an approximate value of \$500 million mostly from Australia, Brazil, India, and the United States. Additionally, it imported over \$150 million of GE canola from Australia and Canada, and \$40 million of soybean oil derived from GE soybeans mostly coming from Argentina.

**e) FOOD AID:**

There are no issues related to imports of GE food aid to Pakistan. Pakistan is a major food aid recipient. Since 2003, Pakistan has received significant quantities of soybean oil derived from GE soybeans. In 2012, the United States donated 7,100 metric tons of soybean oil to Pakistan.

**PART B: POLICY:**

**a) REGULATORY FRAMEWORK:**

Pakistan's regulatory framework is subject to Pakistan's Environmental Protection Act of 1997. Under this act, Pakistan adopted the [National Biosafety Rules](#) in April of 2005, which effectively established the National Biosafety Committee (NBC) as the apex body responsible to review and approve laboratory work, field trials, trade, and commercialization of GE products. The Rules are consistent with the Cartagena Protocol of Biosafety—ratified by Pakistan in 2009—by maintaining a framework for trans-boundary movement, transit, handling, and use of all LMO's.

In addition to the NBC, the Rules create two additional bodies:

- i) The Technical Advisory Committee (TAC), which is responsible for examining applications for approving GE events and making recommendations to the NBC on allowing for laboratory work, field work, or commercialization of the crop variety.
- ii) The Institutional Biosafety Committee (IBC) responsible for undertaking risk assessment, implementing safeguards, and monitoring and inspecting all regulated work that has been authorized by the NBC. The IBC's findings are forwarded to the TAC for review and to formulate recommendations to the NBC.

In 2005, in order to implement the Rules, Pak EPA published the [National Biosafety Guidelines](#). The guidelines provide direction for conducting laboratory and field research, and for the commercial release of GM crops, along with all the necessary forms for implementing these processes.

The NBC is housed at the National Biosafety Centre (Centre) in the newly created Climate Change Division, which reports directly to the Cabinet. There are 17 members of the NBC which include representatives from the ministries of Science and Technology, Commerce and Textile Industry, and Planning and Development. Other agencies include the Pakistan Agriculture Research Council, the Pakistan Atomic Energy Commission, and representatives from the provinces and territories.

**b) APPROVALS:**

In Pakistan cotton is the only GE crop that has been approved for commercial cultivation. Since February of 2012, no new varieties of GE cotton variety have been approved, however, these were approved at the Provincial level by the the Punjab Seed Council (PSC), approving eight biotech cotton varieties for cultivation only in Punjab. While new GE varieties were submitted to the PSC in 2013, these have not been approved due to an outstanding order from the National Biosafety Committee (NBC) stating that approving GE product commercialization is a federal undertaking. It is to note that since 2010, however, the Federal Government has failed to approve any additional varieties for commercial use.

On the multinational company front, field testing of corn by Monsanto, DuPont Pioneer and Syngenta is in process and a few

cases have been submitted to the TAC for their review. Additionally, Monsanto, Nath Seed/Guard, and Bayer are in the process of conducting field trials for insect and herbicide resistance Bt cotton.

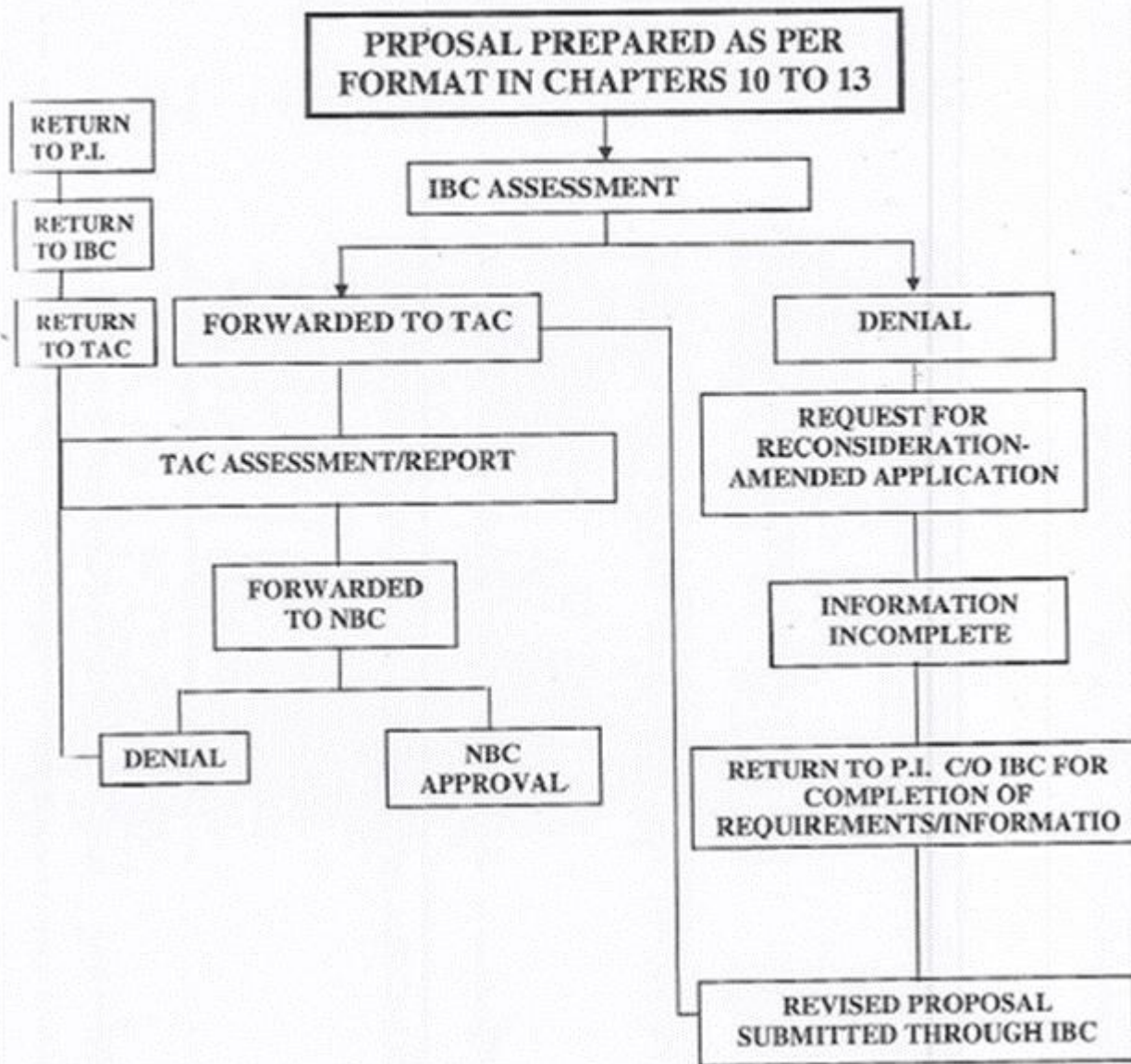
The Bollgard II (stacked gene technology) seed is patented in Pakistan and, as a result, seed companies who want to use the technology will need to enter into a licensing arrangement with Monsanto. The licensing process is expected to minimize pilferage.

The Pakistan Biosafety Rules have explicit timelines for the approval process requesting laboratory, field trials, and commercialization. Submissions should receive a final decision within:

- i. sixty days for work bearing low risk, and work bearing considerable-level risk for lab and green house work
- ii. ninety days for experimental release
- iii. one hundred and twenty days for commercialization

However, when it comes to commercialization, these regulations have been negated.

**PROCESS FLOWCHART FOR REVIEW OF APPLICATIONS FOR  
PERMISSION TO UNDERTAKE LABORATORY, FIELD TRIALS AND  
COMMERCIAL RELEASE OF GMO'S AND THEIR PRODUCTS**



**c) FIELD TESTING**

Although the approval process for the commercialization of new cases of GE crops is stalled, Pakistan is actively conducting field trials as illustrated in Table 1. In addition to Bollgard II cotton and RR Flex (herbicide tolerant) cotton, Bt /Herbicide corn, and drought/ salt tolerant wheat are also under trials.

The Government of Pakistan (GOP) has agreed to provide compensation to third parties negatively impacted by any unapproved biotech during field trial testing.

**d) STACKED EVENT APPROVAL**

The National Biosafety Committee allowed field testing of stacked gene (Cry 1Ac and Cry 2Ab) in cotton developed by the Centre of Excellence in Molecular Biology (CEMB) in Lahore. The director of the CEMB informed that four stacked gene products are in the pipeline and are expected to be submitted to National Biosafety Centre for commercial approval. The National Biosafety Committee considers each event as a separate case and would consider combined “stacked events” as a unique case, regardless if the events have previously been approved for commercialization.

**e) ADDITIONAL REQUIREMENTS**

The product registration system makes use of the existing approval system– Seed Registration and Certification System in Pakistan– with the additional requirement of obtaining biosafety approval from the NBC.

**f) COEXISTENCE**

At present, the GOP has not formulated a policy on coexistence between biotech and non biotech crops.

**g) LABELING**

Pakistan has not made any decision regarding packaged food or feed originating from GE organisms. GE derived edible oil and food is being imported without any restrictions.

**h) TRADE BARRIERS**

There are no laws banning the import of biotech cotton for further processing, biotech oilseeds and meal, biotech feed corn, soybean or other edible oil derived from biotech oilseeds or products containing such oil.

**i) INTELLECTUAL PROPERTY RIGHTS (IPR)**

Pending approval of Plant Breeders’ Rights Act and amendments to the Seed Act are impediments to physical and intellectual investment in Pakistan. Multinational companies and local private companies are reluctant to invest in infrastructure and in Research and Development (R&D) activities due to the lack of enforcement and guarantees to their IPR.

The current Seed Act is outdated and limited to public sector seed companies only. Proposed amendments to the Seed Act would allow R&D in national centers to transfer genetic material to private companies. Punitive measures and fines have been proposed to deter the illegal sale of seed.

The Plant Breeders’ Rights Act would allow for the registration of varieties and the payment of royalties bringing Pakistan into compliance of its WTO commitments under the Trade Related Intellectual Property Rights (TRIPS) Agreement. Farmers would be allowed to exchange seed but would not be permitted to sell the seed on a commercial basis. The delay in passing the acts is perceived as a major impediment for investment in Pakistan by multinational and local seed companies. Reluctance to finalize this legislation is due in part to the desire of Pakistan’s public seed facilities to dominate the basic seed market.

**j) CARTAGENA PROTOCOL RATIFICATION:**

Pakistan ratified the Cartagena Protocol on Biosafety (CPB) on March 2, 2009, and the National Biosafety Rules provide a framework for the transboundary movement, transit, handling, and use of all LMO’s.

**k) INTERNATIONAL TREATIES/FORA**

Pakistan is a member of the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex) and actively participates in discussions on biotechnology.

**l) RELATED ISSUES**

Pakistan considers biotechnology as an important tool that can contribute to national food security on a sustainable basis. Pakistani scientists believe that the gene revolution is an extent of the green revolution that tackles the same issues of food security, and poverty reduction, while encompassing new issues such as environmental conservation, and climate change. As such, it has been incorporated as a tool to combat food insecurity in the GOP’s proposed draft of the National Food Security

and Nutrition Policy.

**m) MONITORING AND TESTING**

The mechanism for monitoring and testing are outline in the Biosafety Guidelines is built upon three tiers as specified in Biosafety Rules 2005 namely IBC, TAC and NBC. The NBC is headed by Secretary Climate Change Division, will be responsible to oversee all lab work, field trials and allow commercial release of GMOs and their products.

**n) LOW LEVEL PRESENCE POLICY**

Pakistan has not considered a low-level presence policy.

**PART C: MARKETING**

**a) MARKET ACCEPTANCE**

Pakistan's agricultural community advocates the utilization of GE technology to increase crop productivity and reduce chemical use. As evidence, nearly 85 percent of the 2013-14 cotton crop is estimated to be planted to transgenic cotton varieties. Industry and consumers have acceptance of GE commodities and processed products. Currently, in response to complaints by some farmers that cotton seed cake is creating problem to mulching animals, the Ministry of National Food Security and Research has tasked Pakistan Agriculture Research Council (PARC) to conduct a comprehensive study of biotech cotton and by products.

**b) PUBLIC/ PRIVATE OPINIONS**

The GOP and agriculture institutions are pro-biotech. Industry and consumers accept GE soybeans, soybean meal, soy oil and other processed food products without opposition. NGO's have raised their voices against agricultural biotechnology with minimal impact on the public debate.

**c) MARKETING STUDIES**

Pak EPA is in planning phase to design a study to assess the level of awareness towards the marketing of GE plants and plant products in the country. According to Ministry of Commerce and Textile Industry, overseas clients have not raised objections to Pakistan's use of GM cotton, especially for products going to the European Union.

**PART D: CAPACITY BUILDING AND OUTREACH**

**a) ACTIVITIES**

The U.S. Government has funded the following capacity building and outreach projects in Pakistan related to agricultural biotechnology.

- In August 2013 USG has scheduled to train two Pak EPA professionals and a TAC member from ministry of National Food Security and Research for a Biotechnology Regulation and Immersion Course at University of Missouri (in Colombia) USA, additionally the group will visit Washington where they will meet their counterparts at USDA, EPA, and FDA.

**b) STRATEGIES AND NEEDS**

Although initial steps have been taken by the Government to recognize that biotechnology will play a key role in food security and climate change mitigation, a disconnect exists between what is being proposed and what is actually happen. To bridge this gap, Pakistani stakeholders need to develop a road map that ensures that a timely, science-based approval process is in place to overcome the current approval process that is fraught with non-sequiturs. The road map would benefit from risk-communication strategies and message mapping so that advocates are able to speak with one voice and communicate effectively at the highest levels of decision making.

Additionally, stakeholders should take a more unified role ensuring that the Public Sector does not waste away capacity building opportunities, which are badly needed and are recognized by the regulators as a key constraint, but who seem disengaged and aloof when the OAA Islamabad offers these opportunities.



## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART E: PRODUCTION AND TRADE**

No production or trade of animal biotechnologies is happening in Pakistan

### **PART F: POLICY**

Biosafety Rules of Government of Pakistan-2005 encompass GE animals. The Pakistan National Biosafety Committee (NBC) and the National Plant and Animal Health Inspection Service (NAPHIS) are responsible for animal biotech activities. Other relevant ministries that play a role are:: Ministry of Commerce and Textile Industry, Ministry of National Food Security and Research, PARC (Animal Sciences Division), National Plant and Health Inspection Service (NAPHIS) and Climate Change Division. A specific regulation of export control list was promulgated in 2004.

In 2005, the GOP notified Export Control List of goods, materials, equipment subject to approval by the ministry of Commerce, Government of Pakistan.

In March 2007, Strategic Export Control Division (SECD) was established in Ministry of Foreign Affairs (MOFA). SECD functions as licensing body for export control of sensitive dual-use goods, technologies, materials and equipment.

Relevant government entities involved in regulation of genetic engineering of animals are; Ministry of Foreign Affairs, Ministry of Commerce and Textile Industry, Ministry of Science and Technology, Climate Change & Planning and Development Divisions.

### **PART G: MARKETING**

There is no public campaign against the use of genetic engineering in the livestock sector. The general awareness to understand genetic engineering related issues is extremely limited.

### **PART H: CAPACITY BUILDING AND OUTREACH**

On various forums GOP has expressed its desire and willingness to jointly work with the USDA in the following areas:

- Quality Assurance/ Biosafety of Animal Vaccines
- Genomic studies of Food Animals as well as Animal Pathogens.